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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,228	03/23/2004	Atsushi Sogabe	226749	3077
23460	7590	07/07/2005	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			SLOBODYANSKY, ELIZABETH	
		ART UNIT		PAPER NUMBER
				1652

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/807,228	SOGABE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 22 April 2005.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 24, 29 and 30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 24 and 29 is/are allowed.  
 6) Claim(s) 30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

The amendment filed April 22, 2005 amending claim 24, canceling claims 25-28 and adding claims 29-30 has been entered for purposes of examination. It does not comply with 37 CFR 1.173(b).

The substitute Sequence Listing and the computer readable form thereof filed April 22, 2005 have been entered, but the paper copy also does not comply with 37 CFR 1.173 (b).

Claims 24, 29 and 30 are pending.

***Specification***

The amendment filed April 22, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amended nucleotide sequence of SEQ ID NO:2.

Applicants assert that "The Sequence Listing has been amended to correct a typographical error in the nucleotide sequence of SEQ ID NO: 2. The corresponding amino acid sequence disclosed in SEQ ID NO: 1 (and recited in SEQ ID NO: 2) is correct. The correct nucleic acid sequence is evident from the source material, namely the amidinohydrolase gene derived from *Alcaligenes faecalis* TE3581 of deposit accession number FERM P-14237 (see SEQ ID NO:2, "original source" information; see also column 4, lines 7-10)" (Remarks,

page 5, last paragraph). It is noted that that Applicants do not point out the changes in the sequence of SEQ ID NO:2 that have been made.

Applicants did not provide any evidence that the nucleotide sequence contained an error. It is feasible that the nucleotide sequence is correct and the amino acid sequence is deduced incorrectly. Arguments of attorney alone cannot take the place of evidence.

Applicant is required to provide evidence that the amendment does not introduce the new matter in the reply to this Office Action.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 30 recites the method for determining Km value for a substrate comprising measuring and comparing the creatine amidinohydrolase activity at

any two different concentrations of a substrate. Applicants indicate support for claim 30 as to be found at column 9, lines 14-39. The text at these lines describes Example 3 where the creatine amidinohydrolase activity was measured using creatine as a substrate at a given concentration and 1/10 concentration.

The Examiner is unable to locate adequate support in the specification for a method using substrates other than creatine and two concentrations other than a given concentration and 1/10 thereof. Thus there is no indication that methods comprising measuring the amidinohydrolase activity with a substrate other than creatine and at concentrations other than 1 and 1/10 thereof were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.121(b).

#### ***Allowable Subject Matter***

Claims 24 and 29 are allowed.

#### ***Response to Arguments***

Applicant's arguments, see Remarks, filed April 22, 2005, with respect to the obviousness rejection (pages 6-7) have been fully considered.

While the examiner does not necessarily agree that there is no motivation to modify the creatine amidinohydrolase of SEQ ID NO:2 of reduced Km value. There is obviously motivation in the art to make the determination of creatine more sensitive and specific that would result from a reduced Km. However, the examiner believes that one of skill in the art would not expect to obtain a mutant creatine amidinohydrolase having the entire combination of properties recited in claims 24, 29 and 30. Therefore, the 103(a) rejection of claim 24 has been withdrawn.

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 6,080,553, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

July 1, 2005